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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/982,272	12/01/1997	THOMAS J. KIPPS	231/003	9087

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	27

DATE MAILED: 05/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
08/898,271	KIPPS
Examiner	**Art Unit**
GIMIE	1644

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ___ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 3/13/01

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) ____ is/are pending in the application. 1-66, 68-84, 87-90, 92-111, 113-122, 125-138

4a) Of the above claim(s) ____ is/are withdrawn from consideration. 1-66, 68-84, 92-98, 103-110

5)☐ Claim(s) ____ is/are allowed.

6)☐ Claim(s) ____ is/are rejected.

7)☐ Claim(s) ____ is/are objected to.

8)☑ Claim(s) ____ are subject to restriction and/or election requirement. 87-90, 99-107, 111, 113-122, 127-138

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on ____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. ____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
4)☐ Interview Summary (PTO-413) Paper No(s). ____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 3/13/02 (Paper No. 25), has been entered.
Claims 91, 112, 123-136 have been canceled.
Claims 1-10, 67 and 83-86 have been canceled previously

Claims 89, 90, 92, 99, 100, 101, 103, 104, 108 ,109 have been amended.

Claims 137-138 have been added.

Claims 11-66, 68-82, 87-90, 92-111, 113-122 and 137-138 are pending.

As indicated previously, claims drawn to methods of expressing CD40L or increasing the concentration of CD40L in cells by transfecting chimeric CD40L molecules which comprise both murine and human CD40L as well as CD40L and TNF-alpha, TNF-beta, Fas ligand, CD70, CD30 ligand, 4-1BBL, Nerve growth factor beta and TRAIL, previously not elected and/or not claimed have been withdrawn from consideration. These claims are drawn to transfected chimeric molecules which differ in structure and function and which are distinct from the originally elected invention of methods which relied upon transfecting CD40L alone.

As indicated previously, claims 11-66, 68-82, 92-98, 103-110 as well as the non-elected species have been withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to the nonelected inventions and species.

In addition, applicant has presented new claims which encompass distinct species previously not claimed and are subject to species election.

3. It does not appear that applicant elected a species in applicant's amendment, filed 3/13/02 (Paper No. 25).
Applicant traverse the Restriction Requirement on the grounds that the claimed CD40 ligand is capable of binding to any of its cognate receptors, preferably human CD40 and that the cells recited in claims 111-122 are indistinct from one another.

However, this is an election of species not Groups and has been treated as an election of species.

Applicant is reminded of the following with respect to the election of species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Given that applicant does not admit or provide evidence the species are obvious variants, the species requirement is maintained for the reasons of record.

4. As indicated previously, applicant is required to elect a species from the following or admit that these are obvious variants.

This application contains claims directed to the following patentably distinct species of the originally present invention of Group I: wherein the CD40L specificity is:

A) murine CD40L or
B) human CD40L.

These species are distinct because their structures, interactions, modes of action are different.

In addition, this application contains claims directed to the following patentably distinct species of the originally present invention of Group I: wherein the cell is:

A) neoplastic B cell,
B) CLL cell,
C) neoplastic T cell,
D) neoplastic dendritic cell,
E) neoplastic monocyte cell,
F) neoplastic myelomonocyte cell,
G) breast tumor cell,
H) ovarian tumor cell,

I) lung tumor cell, or
J) cell derived from connective tissue surrounding neoplastic cells.

Also, if applicant intends to include non-neoplastic cells, such as B cell, and dendritic cells, then these normal cells would also be subject to species election.

These species are distinct because their structures, interactions, modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

5. In addition, applicant is required to elect a species from the following.

In addition, this application contains claims directed to the following patentably distinct species of the originally presented elected invention wherein the domain /subdomain of the non-human CD40 ligand is:

A) Domain I,
B) Domain II,
C) Domain III, or
D) Domain IV.

In addition, this application contains claims directed to the following patentably distinct species of the originally presented elected invention wherein the nucleic acid comprises:

A) SEQ ID NO: 3,
B) SEQ ID NO: 4,
C) SEQ ID NO: 5,
D) SEQ ID NO: 6,
E) SEQ ID NO: 7, or
F) SEQ ID NO: 20.

These species are distinct because their structures and physicochemical properties differ.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6. In order to advance prosecution, the following is noted.

Applicant should clearly elect an invention and species that reads on introducing murine or human CD40 ligand into a $CD40^+$ human cell.

Further, applicant should clearly elect whether this nucleic acid is chimeric or not and, if chimeric, which domain of non-human CD40 ligand is transfected.

Here, too, applicant should clearly elect a SEQ ID NO. and indicate how it reads on the elected Domain.

Applicant is reminded to elect the $CD40^+$ human cell type.

Also, applicant is reminded of issues of written description and enablement under 35 USC 112, first paragraph, with respect to CD40 ligand receptor (versus CD40).

Applicant is invited to clearly direct the examiner to the metes and bounds and scope of the claimed domains and subdomains recited in the claims to avoid issues of written description and enablement under 35 USC 112, first paragraph.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
May 30, 2002